James Edward Polli

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EMPLOYMENT:

July, 2007-Present	University of Maryland School of Pharmacy - Baltimore, MD Professor and Vice-Chair; Ralph F. Shangraw/Noxell Endowed Chair in Industrial Pharmacy and Pharmaceutics Research interests evolve around oral biopharmaceutics and include gastrointestinal drug delivery, mechanisms of drug absorption, oral solid dosage forms, prodrugs, and the biopharmaceutic issues relating to the performance and regulation of drug products. Senior Faculty member of Research Training in Gastroenterology (2 T32 DK067872-06).
July, 1999-June, 2007	Associate Professor of Pharmaceutical Sciences
Dec. 1993-July, 1999	Assistant Professor of Pharmaceutical Sciences

OTHER RESEARCH EXPERIENCE:

1989-Dec. 1993	University of Michigan College of Pharmacy - Ann Arbor, MI Graduate Student
Summer 1989	Merck Research Laboratories - West Point, PA Research Scientist Intern
April, 1989	United States Pharmacopeial Convention, Inc. - Rockville, MD Drug Standards Extern
Summer 1988	Merck Pharmaceutical Manufacturing Division - West Point, PA Process Pharmacist Intern
1985-1987	PCPS Industrial Pharmacy Laboratory - Philadelphia, PA Undergraduate Research Associate
Summer 1987	Pfizer, Inc. - Groton, CT A.S.P.-N.P.C. Research-Intensive Summer Intern

EDUCATION:

1989-1993	University of Michigan College of Pharmacy Doctor of Philosophy in Pharmaceutics. (b)(6) student. McNeil-AFPE First Year Graduate Fellowship. Eli Lilly Fellowship. AFPE-Charles J. Lynn Memorial Fellowship. Glaxo-AFPE Manufacturing/Industrial Pharmacy Fellowship. NACDS-AFPE "Springboard to Teaching" Fellowship. Rackham Predoctoral Fellowship. Walter F. Enz-Upjohn Award.

1984-1989 Philadelphia College of Pharmacy and Science
Graduated Magna Cum Laude with Bachelor of Science in Pharmacy. Near (b)(4) student. Dean's List each semester. Rho Chi Honor Society. Registered Pharmacist in Michigan.

PROFESSIONAL AWARDS:
1998 AAPS New Investigator Award in Pharmaceutics and Pharmaceutical Technology
2008 AAPS Fellow

ACADEMIC PAPERS:

Polli, J.E. and Amidon, G.L. (1995): In vitro characterization of sodium glycocholate binding to cholestyramine resin. *J. Pharm. Sci*. **84:**55-61.

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Polli, J.E. (1999): Dependence of "in vitro-in vivo correlation" analysis acceptability on model selections. *Pharm. Dev. Technol*. **4**:89-96.

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Lentz, K.A., Hayashi, J., Lucisano, L.J. and Polli, J.E. (2000): Development of a more rapid, reduced serum culture system for Caco-2 monolayers and application to biopharmaceutics classification system. *Int. J. Pharm.* **200(1)**: 41-51.

Polli, J.E. IVIVR vs. IVIVC. (2000): *Dissolution Technologies* **7(3):** 6-16.

Lentz, K.A., Polli, J.W., Wring, S.A., Humphreys, J.E., and Polli, J.E. (2000): Influence of passive permeability on apparent P-glycoprotein kinetics. *Pharm. Res.* **17**:1456-1460.

Sheskey, P., Pacholke, K., Sackett, G., Maher, L., and Polli, J.E. (2000): Roll compaction granulation of a controlled-release matrix tablet containing HPMC: Effect of process scale-up on robustness of tablets and predicted in vivo performance. Part II. *Pharm. Tech.* **24(11)**: 30-52.

Zlatic, T.D. and committee members (Alkana, R.L., Bradberry, J.C., Chalmers, R.K., Polli, J.E., Boyce, E.C., and Wadelin, J.W.) (2001): Integrating education: chair report for the academic affairs committee. *Amer. J. Pharm. Ed*. **64**:8S-15S.

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Gharat, L., Taneja, R., Weerapreeyakul, N., Rege, B., Polli, J.E., and Chikhale, P. (2001): Intracellular bioreductive activation, uptake, and transport of an anticancer drug delivery system across intestinal Caco-2 cell monolayers. *Int. J. Pharm*. **219**:1-10.

Polli, J.E. and McLean A.M. (2001): Novel direct curve comparison metrics for bioequivalence. *Pharm. Res*. **18**:734-741.

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Tolle-Sander, S., Rautio, J., Wring, S., Polli, J.W., and Polli, J.E. (2003): Midazolam exhibits characteristics of a highly permeable P-glycoprotein substrate. *Pharm. Res*. **20**:757-764.

Tolle-Sander, S., Grill, A., Joshi, H., Kapil, R., Persiani, S., and Polli, J.E. (2003): Characterization of dexloxiglumide in vitro biopharmaceutic properties and active transport. *J. Pharm. Sci*. **92**:1968-1980.

Polli, J.E., Kim, S., and Martin, B. (2003): Dose uniformity from split tablets and Veterans Affairs policy. *J. Managed Care Pharm*. **9**:305-311.

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Balakrishnan, A., Rege, B.D., Amidon, G.L., and Polli, J.E. (2004): Surfactant-mediated dissolution: contributions of solubility enhancement and relatively low micelle diffusivity. *J. Pharm. Sci*. **93**:2064-2075.

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xBalakrishnan, A., Hussainzada, N., Gonzalez, P., Bermejo, M., Swaan, P.W., and Polli, J.E. (2007): Bias in estimation of transporter kinetic parameters from over-expression systems: interplay of transporter expression level and substrate affinity. *J. Pharmacol. Exp. Ther*. **320**:133-144.

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of segmental differences and correlation with in vitro results. *Biopharmaceutics & Drug Disposition*. **28**:229–239.

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Polli, J.E, Hoag, S.W., and Flank, S. (2009): Near Infrared Spectrophotometric Comparison of Authentic and Suspect Pharmaceuticals. *Pharm. Tech*. **33(8)**:46-52.

Zheng, X., Ekins, S., Raufman, J., and Polli, J.E. (2009): Computational models for drug inhibition of the human apical sodium-dependent bile acid transporter. DOI: 10.1021/mp900163d. *Mol. Pharmaceutics* 5:1591-1603.

Teksin, Z.S., Seo, P.R., and Polli, J.E. (2010): Comparison of Drug Permeabilities and BCS Classification: Three Lipid Component PAMPA System Method versus Caco-2 Monolayers. DOI: 10.1208/s12248-010-9176-2. *AAPS J*. **12**:238-241.

Tompkins, L., Lynch, C., Haidar, S., Polli, J.E., and Wang, H. (2010): Effects of Commonly Used Excipients on the Expression of CYP3A4 in Colon and Liver Cells. DOI 10.1007/s11095-010-0170-2. *Pharm. Res.* **27**:1703–1712.

Selen, A., Cruañes, M.T., Müllertz, A., Dickinson, P.A., Cook, J.A., Poll, J.E., Kesisoglou; F., Crison; J., Johnson, K.C., Muirhead, G.T., Schofield, T., and Tsong, Y. (2010): Conference Report: Applied Biopharmaceutics and Quality by Design for Dissolution/Release Specification Setting: Product Quality for Patient Benefit. DOI: 10.1208/s12248-010-9206-0. *AAPS J.* **12**:465-472.

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Zheng, X. and Polli, J.E. (2010): Synthesis and In Vitro Evaluation of Potential Sustained Release Prodrugs via Targeting ASBT. DOI:10.1016/j.ijpharm.2010.06.039. I*nt. J. Pharm.*. **396**: 111–118.

Diao, L., Shu, Y., and Polli, J.E. (2010): Uptake of pramipexole by human organic cation transporters. DOI: 10.1021/mp100036b. *Mol. Pharmaceutics* **7**: 1342–1347.

Cook, J.A., Davit, B.M., and Polli, J.E. (2010): Impact of Biopharmaceutics Classification System-based Biowaivers. DOI:10.1021/mp1001747. *Mol. Pharmaceutics*. **7**: 1539–1544.

Zheng, X. and Polli, J.E. (2010): Identification of Inhibitor Concentrations to Efficiently Screen and Measure Inhibition Ki Values against Solute Carrier Transporters. DOI: 10.1016/j.ejps.2010.05.013. *Eur. J. Pharm Sci*. **41**:43-52.

Zheng, X., Diao, L., Ekins, S., and Polli, J.E. (2010): Why We Should be Vigilant: Drug Cytotoxicity Observed with In Vitro Transporter Inhibition Studies. doi:10.1016/j.bcp.2010.06.012. *Biochem. Pharmacol*. **80**:1087–1092.

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BOOK CHAPTERS:

Polli, J.E.:"In Vitro-In Vivo Relationships of Several "Immediate" Release Tablets Containing a Low Permeability Drug". In Young, D., Devane, J.G. and Butler, J. (eds.), *In Vitro-In Vivo Relationships; Plenum*: New York, 1997, pp. 191-199.

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RECENT ABSTRACTED POSTERS:

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Williams, I., Johnson, D., and and Polli, J.E. (2011): Mechanistic iInterpretation of Conventional Michelis-Menten Parameters. Emerging Researchers National (ERN) Conference in STEM, Washington DC.

RECENT INVITED LECTURES:

"In Vitro Studies Are Sometimes Better than Conventional Human Pharmacokinetic In Vivo Studies in Assessing Bioequivalence of Immediate-release Solid Oral Dosage Forms". Joseph B. Schwartz Memorial Symposium: Advances in Industrial Pharmacy. Philadelphia, PA. March, 2009.

"Cell Culture Methods and Permeability". Strategies for Oral Drug Delivery Workshop, Garmisch Partenkirchen, Germany. March, 2009.

"Dissolution Methodologies and IVIVC". Strategies for Oral Drug Delivery Workshop, Garmisch Partenkirchen, Germany. March, 2009.

"Intestinal Drug Transport: Mechanistic Understanding". AAPS Workshop on Evolving Science and Technology in Physical Pharmacy and Biopharmaceutics, Baltimore, MD. May, 2009.

"Bioequivalence between dogs and humans". Animal Health Institute Quality by Design Workshop, Arlington, VA. Oct 2009.

"In Vitro Release and Biopharm Perspective". FDA Workshop on ER, Silver Spring, MD. Nov 2009.

"Critical Formulation Factors for Establishing Equivalence of Modified Release Dosage Forms". AAPS Annual Meeting, Los Angeles, CA. Nov 2009.

"Regulatory approaches to waive in vivo BE studies". GlaxoSmithKline, Parsippany, NJ. Nov 2009.

"PK and BE study design". GlaxoSmithKline, Parsippany, NJ. Nov 2009.

"Cell Culture Methods and Permeability". Strategies for Oral Drug Delivery Workshop, Lake Tahoe, NV. March 2010.

"Dissolution Methodologies and IVIVC". Strategies for Oral Drug Delivery Workshop, Lake Tahoe, NV. March 2010.

"Biopharmaceutics". 52nd Annual International Industrial Pharmaceutical Research and Development Conference, University of Wisconsin, Merrimac, WI, June 2010.

"Dissolution Profile Similarity and IVIVC". 2nd International Regulatory Workshop on Bioequivalence, Bioanalysis, Dissolution and Biosimilars, FIP/EUFEPS/AAPS/Hungarian Society for Pharmaceutical Sciences, Budapest, Hungary, June 2010.

"In Vitro Studies Sometimes are Better than In Vivo Studies. When and Why". 2nd International Regulatory Workshop on Bioequivalence, Bioanalysis, Dissolution and Biosimilars, FIP/EUFEPS/AAPS/Hungarian Society for Pharmaceutical Sciences, Budapest, Hungary, June 2010.

"Bile acid transporter". University of Michigan Pharmaceutical Sciences Symposium. Ann Arbor, MI. Oct., 2010.

"Dissolution Specifications: Consideration of Dissolution and Permeation Kinetics in Overall Absorption Kinetics". AAPS Annual Meeting, New Orleans, LA. Nov 2010.

"Biopharmaceutical Basis of Formulation Development". Canadian Society of Pharmaceutical Scientists annual meeting, Toronto, Canada. December, 2010.

"Solute Carrier Transporters in Drug Absorption and Drug-Drug Interactions". 2nd Product Development Forum for the Controlled Release Society, Orlando, FL. January 2011.

PROFESSIONAL PUBLICATIONS:

Polli, J.E. (1992): Current research in gene therapy: what pharmacists need to know. *NEWSLINE for Pharmacists* **1(10):**4-7.

Polli, J.E. and Polli, G.P. (1993): Employment opportunities for pharmacists in the pharmaceutical industry. *NEWSLINE for Pharmacists* **2(2):**3-7.

Polli, J.E. (1993): Implementing pharmaceutical care programs. *NEWSLINE for Pharmacists* **2(4):**4-7.

Polli, J.E. (1995): History of drug regulation and formulary development. *NEWSLINE for Pharmacists* **4(4):**3-7.

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Polli, J.E. (1995): Career Alternative - Pharmaceutics. *Pharmacy Student* **25(2):**20-21.

Polli, J.E. and Hoag, S.W. (2004): Near-Infrared Technology Detects Counterfeit Drugs. *US Pharmacist* **Feb**:104-6.

Polli, J.E., Schoneker, D.R., and Hoag, S.W. (2005): Counterfeit Drug Products: Problems and Solutions. *AAPS Newsletter* **July**: 20-22.

SELECTED PROFESSIONAL SERVICE:

2004-2008	A.A.P.S. Pharmaceutics and Drug Delivery Served as Vice-Chair, Chair-Elect, and then Chair. Served on 2006 Annual Meeting Programming Committee and several other AAPS committees.
2008-2009	A.A.P.S. Manufacturing and Science Served as Past-Chair.
1999-present	AAPSPharmSci, Editorial Advisory Board
2000-present	Pharmaceutical Technology, Editorial Advisory Board
2003-present	Molecular Pharmaceutics, Editorial Advisory Board
2004-present	Journal of Pharmaceutical Sciences, Editorial Advisory Board
2004-present	European Journal of Pharmaceutical Sciences, Editorial Advisory Board
2006-Present	Pharmaceutical Research, Editorial Advisory Board Serving as Associate Editor (2009 – Present)

2005-2010	USP Biopharmaceutics Expert Committee Served as Vice-Chair.
2009-Present	FDA Advisory Committee for Pharmaceutical Science and Clinical Pharmacology
2010-present	A.A.P.S. Member-at-large

Date: January 30, 2011